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A phase II trial of gemcitabine in patients with 5-FU-refractory pancreas cancer.

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PURPOSE: To assess the effect of gemcitabine in patients with metastatic pancreas cancer that had progressed despite prior treatment with 5-FU. **PATIENTS AND METHODS:** Seventy-four patients were enrolled in this multicenter trial. Alleviation of cancer-related symptoms was the primary endpoint. Sixty-three patients completed a pain stabilization period and were treated with gemcitabine. Clinical Benefit Response was defined as a $\geq 50\%$ reduction in pain intensity, $\geq 50\%$ reduction in daily analgesic consumption, or ≥ 20 point improvement in KPS that was sustained for ≥ 4 consecutive weeks. **RESULTS:** Seventeen of 63 pts (27.0%) attained a Clinical Benefit Response (95% CI: 16.0%-38.0%). The median duration of Clinical Benefit Response was 14 weeks (range: 4-69 weeks). Median survival for patients treated with gemcitabine was 3.85 months (range: 0.3-18.0+ months). Therapy was generally well-tolerated with a low incidence of grade 3 or 4 toxicities. **CONCLUSION:** Systematic assessment of subjective outcomes can be used to evaluate the clinical impact of new therapies for pancreas cancer, a highly symptomatic disease. Our findings suggest that gemcitabine is a useful palliative agent in patients with 5-FU-refractory pancreas cancer.

Publication Types:

- Clinical trial
- Clinical trial, phase ii
- Multicenter study

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